IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Bernhard H. van LENGERICH	T. C. Art Unit : 1612
Appl. No.	: 09/782,320	Examiner : ROBERTS, Lezah W.
Filed	: February 13, 2011	Confirmation No. : 9819

For : **EMBEDDING AND ENCAPSULATION OF SENSITIVE COMPONENTS INTO A MATRIX TO OBTAIN DISCRETE CONTROLLED RELEASE PARTICLES**

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Appeal Brief - Patents
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir :

This appeal is from the final rejection of claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 94, 95-97, 101, 103, 105, 108, 109, and 110, as set forth in the Final Office Action dated November 23, 2010. A Notice of Appeal in response to the November 23, 2010 Final Office Action was filed on April 1, 2011 with a request for a one month extension of time to extend the due date to April 1, 2011. An Amendment After Final Rejection Under 37 C.F.R. § 1.116 was filed by the two month due date on January 21, 2011, to which the Examiner issued an Advisory Action, dated March 1, 2011. A telephonic interview was conducted on April 5, 2011, and Examiner Interview Summary was issued on April 7, 2011. Pursuant to the Examiner Interview and Interview Summary, a Second Amendment After Final Rejection

Under 37 C.F.R. § 1.116 And Record of Telephonic Interview was filed on April 20, 2011, to which the Examiner issued an Advisory Action, dated June 30, 2011. A request for a one month extension of time is being filed concurrently herewith to extend the period for filing an Appeal Brief until July 1, 2011.

This is the second Appeal filed in this case, with the first Appeal Brief being filed via certificate of facsimile transmission on January 12, 2007 with the then requisite fee of $500.00. All rejections were withdrawn in a September 4, 2008 Office Action reopening prosecution. A final Board decision was not rendered on that previous Appeal. Accordingly, pursuant to MPEP 1204.01 the $500.00 previously paid Appeal fee should be applied to the present Appeal, and so only the $40.00 increase from the previously paid fee of $500.00 to the current requisite $540.00 fee for filing an Appeal Brief under 37 C.F.R. § 41.20(b)(2), and the $130.00 fee for an additional one-month extension of time are being paid concurrently herewith. However, if for any reason the necessary fee is not associated with this file, or the fee as submitted is inadequate, the Commissioner is authorized to charge the fee for the Appeal Brief and any necessary extension of time fees to Deposit Account No. 19-0089 (P32853).

TABLE OF CONTENTS

I. Real Party In Interest..... 4

II. Related Appeals and Interferences..... 5

III. Status of Claims..... 6

IV. Status of Amendments..... 7

V. Summary of Claimed Subject Matter..... 8

VI. Grounds of Rejection to be Reviewed on Appeal..... 14

VII. Argument..... 16

A. Relevant Legal Principles..... 16

B. Claims 31, 59, 108 And 109 Are Not Properly Rejected Under 35 U.S.C. 112, First Paragraph..... 18

C. Claims 31, 59, 108 And 109 Are Not Properly Rejected Under 35 U.S.C. 112, Second Paragraph..... 22

D. Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 73, 75, 79, 81-83, 85, 91-93, 95-97, 101, 103, 105, 108, and 109 are not properly rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (USP 4,938,967) in view of Eden et al (USP 4,755,397)..... 24

E. Claims 42, 69, 70, 84, and 108-110 are not properly rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (USP 4,938,967) in view of Eden et al (USP 4,755,397) in further view of Jane et al (USP 5,397,834)..... 36

VIII. Conclusion..... 39

IX. Claims Appendix..... 40

X. Evidence Appendix..... 51

XI. Related Proceedings Appendix..... 52

I. REAL PARTY IN INTEREST

The real party in interest is GENERAL MILLS IP HOLDINGS II, LLC by virtue of assignments recorded in the parent application 09/269763, now U.S. Patent No. 6,190,591.

II. RELATED APPEALS AND INTERFERENCES

This is the second Appeal filed in this case, with the first Appeal Brief being filed via certificate of facsimile transmission on January 12, 2007. All rejections were withdrawn in a September 4, 2008 Office Action reopening prosecution. A final Board decision was not rendered on that previous Appeal. Appellant is not aware of any other prior or pending appeals, interferences, or judicial proceedings which may be related to, directly affect, or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 94, 95-97, 101, 103, 105, 108, 109, and 110 are pending, with claim 94 being the only withdrawn claim. Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105, 108, 109, and 110 stand finally rejected and are the subject of this appeal.

Claims 1-24, 32-33, 36, 41, 43-45, 47-49, 51, 60, 63, 68, 71-72, 74, 76-78, 80, 86-90,98-100, 102, 104, and 106-107 were previously cancelled.

Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61, 62, 64-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103, 105, and 108-110 involved in the appeal are reproduced in the Claims Appendix attached hereto.

IV. STATUS OF AMENDMENTS

An Amendment After Final Rejection Under 37 C.F.R. § 1.116 was filed on January 21, 2011, without amending the claims. The Examiner issued an Advisory Action, dated March 1, 2011, advising that the rejections under 35 U.S.C. 112 first and second paragraphs were withdrawn as to the term "modified starch" but were maintained as to the term "derivatives of polyvinyl acetate." The Advisory Action indicated that the rejections under 35 U.S.C. 103(a) were maintained. A telephonic interview was conducted on April 5, 2011, and an Examiner Interview Summary was issued on April 7, 2011. Pursuant to the Examiner Interview and Interview Summary, a Second Amendment After Final Rejection Under 37 C.F.R. § 1.116 And Record of Telephonic Interview was filed on April 20, 2011, without amending the claims. The Examiner issued an Advisory Action, dated June 30, 2011, advising that the rejections under 35 U.S.C. 112 first and second paragraphs are maintained as to the term "derivatives of polyvinyl acetate. The Advisory Action indicated that the rejections under 35 U.S.C. 103(a) were also maintained. The Advisory Action also indicates that claims 42, 69, 70, 84, and 108 are objected to, but no objections to those claims are set forth in the Advisory Action or were previously raised in the November 23, 2010 Final Rejection. These same claims were rejected under 35 U.S.C. 103(a) involving the Jane et al reference, but there is no objection involving these claims, and accordingly it is believed that the indication of an objection to claims 42, 69, 70, 84, and 108 is in error.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Initially, Appellant notes that the following descriptions are made with respect to the independent claims on appeal and include references to particular parts of the specification. As such, the following descriptions are merely exemplary and are not a surrender of other aspects of the present invention that are also enabled by the present specification, as well as those descriptions that are directed to equivalent structures or methods.

A. Claim 25

Independent claim 25 is directed to an encapsulated product comprising discrete, solid particles having a substantially uniform shape and a diameter of up to about 10 mm. See page 7 lines 4-6 and 17-20, page 9 line 26 to page 10 line 1, and page 28 line 30 to page 29 line 8 and FIGS. 4 and 5. Each particle comprises an encapsulant dispersed throughout a plasticized mass comprising starch which is not substantially destructured or dextrinized, and at least one component for controlling the rate of release of the encapsulant. The plasticized mass comprises at least about 40% by weight of at least one matrix material, based on the weight of the final product, and at least one plasticizer comprising water. The encapsulant and plasticized matrix material form an at least substantially homogeneous mixture. The amount of the encapsulant is from about 1% by weight to about 85% by weight, based upon the weight of the matrix material. See page 6 lines 2-9, page 7 lines 4-12, page 8 lines 2-16, page 8 line 22 to page 9 line 15, page 10

lines 3-15, page 11 lines 2-16, page 11 line 27 to page 14 line 3, page 21 lines 11-19, page 22 line 12 to page 23 line 23, page 26 lines 17-19, page 29 lines 10-11, page 32 lines 14-15, and page 33 lines 24-26. The encapsulant comprises at least one pharmaceutical component, neutraceutical component, nutritional component, fragrance component, or biologically active component. See page 11 lines 19-23, and page 14 line 9 to page 10 line 2.

B. Claim 27

Independent claim 27 is also directed to an encapsulated product comprising discrete, solid particles having a substantially uniform shape and a diameter of up to about 10 mm. See page 7 lines 4-6 and 17-20, page 9 line 26 to page 10 line 1, and page 28 line 30 to page 29 line 8 and FIGS. 4 and 5. Each particle comprises an encapsulant dispersed throughout a plasticized mass comprising starch which is not substantially destructured or dextrinized, and at least one component for controlling the rate of release of the encapsulant. The plasticized mass comprises at least about 40% by weight of at least one matrix material, based on the weight of the final product, and at least one plasticizer. The encapsulant and plasticized matrix material form an at least substantially homogeneous mixture. The amount of the encapsulant is from about 1% by weight to about 85% by weight, based upon the weight of the matrix material. See page 6 lines 2-9, page 7 lines 4-12, page 8 lines 2-16, page 8 line 22 to page 9 line 15, page 10 lines 3-15, page 11 lines 2-16, page 11 line 27 to page 14 line 3, page 21 lines 11-19, page 22 line 12

to page 23 line 23, page 26 lines 17-19, page 29 lines 10-11, page 32 lines 14-15, and page 33 lines 24-26. The encapsulant comprises at least one pharmaceutical component, neutraceutical component, nutritional component, fragrance component, or biologically active component. See page 11 lines 19-23, and page 14 line 9 to page 15 line 2. The encapsulant is coated with a film-forming material prior to dispersion within the plasticized mass. See page 21 line 20 to page 22 line 11, page 34 lines 10-16, the Abstract, last three lines, and FIG. 4.

C. Claim 52

Independent claim 52 is also directed to an encapsulated product comprising discrete, solid particles having a substantially uniform shape. See page 7 lines 4-6 and 17-20, page 9 line 26 to page 10 line 1, and page 28 line 30 to page 29 line 8 and FIGS. 4 and 5. Each particle comprises an encapsulant dispersed throughout a plasticized matrix material comprising starch which is not substantially destructured or dextrinized, and at least one component for controlling the rate of release of the encapsulant. The plasticized matrix material comprises at least one member selected from the group consisting of durum wheat, semolina, wheat flour, wheat gluten, soy protein, hydrocolloids, casein, and gelatin, and at least one plasticizer comprising water. The amount of the plasticized matrix material is least about 40% by weight, based on the weight of the final product. The encapsulant and plasticized matrix material form an at least substantially homogeneous mixture. The amount of the encapsulant is from about 1% by weight to

about 85% by weight, based upon the weight of the matrix material. See page 6 lines 2-9, page 7 lines 4-12, page 8 lines 2-16, page 8 line 22 to page 9 line 15, page 10 lines 3-15, page 11 lines 2-16, page 11 line 27 to page 14 line 3, page 21 lines 11-19, page 22 line 12 to page 23 line 23, page 26 lines 17-19, page 29 lines 10-11, page 32 lines 14-15, page 33 lines 17-26, page 42 Table 2, and FIG. 3. The encapsulant comprises at least one pharmaceutical component, neutraceutical component, nutritional component, fragrance component, or biologically active component. See page 11 lines 19-23, and page 14 line 9 to page 15 line 2.

D. Claim 54

Independent claim 54 is also directed to an encapsulated product comprising discrete, solid particles having a substantially uniform shape. See page 7 lines 4-6 and 17-20, page 9 line 26 to page 10 line 1, and page 28 line 30 to page 29 line 8 and FIGS. 4 and 5. Each particle comprises an encapsulant dispersed throughout a plasticized matrix material comprising starch which is not substantially destructured or dextrinized, and at least one component for controlling the rate of release of the encapsulant. The plasticized matrix material comprises at least one member selected from the group consisting of durum wheat, semolina, wheat flour, wheat gluten, soy protein, hydrocolloids, casein, and gelatin, and at least one plasticizer. The amount of the plasticized matrix material is least about 40% by weight, based on the weight of the final product. The encapsulant and plasticized matrix material form an at least substantially homogeneous mixture. The

amount of the encapsulant is from about 1% by weight to about 85% by weight, based upon the weight of the matrix material. See page 6 lines 2-9, page 7 lines 4-12, page 8 lines 2-16, page 8 line 22 to page 9 line 15, page 10 lines 3-15, page 11 lines 2-16, page 11 line 27 to page 14 line 3, page 21 lines 11-19, page 22 line 12 to page 23 line 23, page 26 lines 17-19, page 29 lines 10-11, page 32 lines 14-15, page 33 lines 17-26, page 42 Table 2, and FIG. 3. The encapsulant comprises at least one pharmaceutical component, neutraceutical component, nutritional component, fragrance component, or biologically active component. See page 11 lines 19-23, and page 14 line 9 to page 15 line 2. The encapsulant is coated with a film-forming material prior to dispersion within the plasticized mass. See page 21 line 20 to page 22 line 11, page 34 lines 10-16, the Abstract, last three lines, and FIG. 4.

E. Claim 83

Independent claim 83 is also directed to an encapsulated product comprising discrete, solid particles having a substantially uniform shape. See page 7 lines 4-6 and 17-20, page 9 line 26 to page 10 line 1, and page 28 line 30 to page 29 line 8 and FIGS. 4 and 5. Each particle comprises an encapsulant dispersed throughout a plasticized matrix material comprising starch which is not substantially destructured or dextrinized. The plasticized matrix material comprises at least one member selected from the group consisting of durum wheat, semolina, vital wheat gluten, soy protein, hydrocolloids, casein, and gelatin, and at least one plasticizer comprising water. The amount of the

plasticized matrix material is least about 40% by weight, based on the weight of the final product. The encapsulant and plasticized matrix material form an at least substantially homogeneous mixture. The amount of the encapsulant is from about 3% by weight to about 50% by weight, based upon the weight of the matrix material. See page 6 lines 2-9, page 7 lines 4-12, page 8 line 22 to page 9 line 15, page 10 lines 3-15, page 11 lines 2-16, page 11 line 27 to page 13 line 2, page 21 lines 11-19, page 22 line 12 to page 23 line 14, page 26 lines 17-19, page 29 lines 10-11, page 32 lines 14-15, page 33 lines 17-26, page 42 Table 2, and FIG. 3. The encapsulant comprises at least one pharmaceutical component, neutraceutical component, nutritional component, fragrance component, or biologically active component. See page 11 lines 19-23, and page 14 line 9 to page 15 line 2.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 31, 59, 108 and 109 are properly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the March 1, 2011 Advisory Action, the Examiner advised that Appellant's arguments presented in the January 21, 2011 response were persuasive regarding the term "modified starch" and the rejection was withdrawn as to the term "modified starch," but the rejection is maintained as to the term "derivatives of polyvinyl acetate." The June 30, 2011 Advisory Action is consistent in only addressing the recitation of a polyvinyl acetate derivative.

2. Whether claims 31, 59, 108, and 109 are properly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the March 1, 2011 Advisory Action, the Examiner advised that Appellant's arguments presented in the January 21, 2011 response were persuasive regarding the term "modified starch" and the rejection was withdrawn as to the term "modified starch," but the rejection is maintained as to the term "derivatives of polyvinyl acetate." The June 30, 2011 Advisory Action is consistent in only addressing the recitation of a polyvinyl acetate derivative.

3. Whether claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 73, 75, 79, 81-83, 85, 91-93, 95-97, 101, 103, 105, 108, and 109 are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (U.S. Patent No. 4,938,967) in view of Eden et al (U.S. Patent No. 4,755,397).

4. Whether claims 42, 69, 70, 84, and 108-110 are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (U.S. Patent No. 4,938,967) in view of Eden et al (U.S. Patent No. 4,755,397) in further view of Jane et al (U.S. Patent No. 5,397,834.

VII. ARGUMENT

A. RELEVANT LEGAL PRINCIPLES

Obviousness

The appropriate starting point for a determination of obviousness is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 U.S.P.Q. 459, 466 (1966):

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

"A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). The relevant question is "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *Id.* "We must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention." *Innogenetics, N.V. v. Abbott Labs.*, 512, F.3d 1363, 1374 n.3 (Fed. Cir. 2008).

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." *In re Rijckaert*, 9 F.3d, 1531, 1532 (Fed. Cir. 1993), citing *In re Fine*, 837 F.2d 1071, 1074,5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), quoted with approval in *KSR Int'l Co. v. Teleflex Inc., supra.*

"[I]t is not enough to simply show that the references disclose the claim limitations; in addition, 'it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does.'" *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617, F.3d 1296, 1303 (Fed. Cir. 2010) (quoting *KSR Int'l Co. v. Teleflex Inc., supra).*

Ultimately therefore, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

Further, it is also necessary for the Examiner to properly construe what an applied reference *fairly* teaches or discloses. See, e.g., *In re Fracalossi and Wajer*, 681 F.2d 792 (CCPA 1982).

B. Claims 31, 59, 108 And 109 Are Not Properly Rejected Under 35 U.S.C. 112, First Paragraph, As Failing To Comply With The Written Description Requirement Because The Claims Contain Subject Matter Which Was Not Described In The Specification In Such A Way As To Reasonably Convey To One Skilled In The Relevant Art That The Inventor(s), At The Time The Application Was Filed, Had Possession Of The Claimed Invention.

In the March 1, 2011 Advisory Action Appellant's arguments presented in the January 21, 2011 response were indicated as persuasive regarding the term "modified starch" and the rejection is withdrawn as to that term. However, regarding the derivatives of polyvinyl acetate it was indicated in the March 1, 2011 Advisory Action that the rejection was being maintained. The June 30, 2011 Advisory Action is consistent in only addressing the recitation of a polyvinyl acetate derivative.

In the Final Rejection of November 23, 2010, the Examiner alleges that the term "polyvinyl acetate and derivatives thereof" is unclear since Appellant's specification does not define at what point does modifying the core compound lead to a different compound that would not be considered a derivative encompassed by the instant invention.

As set forth in the August 18, 2010 Amendment, the Manual of Patent Examining Procedure states,

> What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. >See also *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005)("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge. As each field evolves, the balance also evolves between what is known and what is added by each

> inventive contribution.").< If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient").

MPEP § 2163 Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement [R-5].

As pointed out in the August 18, 2010 Amendment, the term "derivative" is used extensively in the USPTO class definitions as exemplified by a search in the USPTO online Manual of Classification for the term "derivative" (http://search.usa.gov/search?query=+derivative&affiliate=uspto.gov&locale=en&m=&scope_id=PatentClass&commit=Search):

> Results 1-10 of about 184 for 'derivative' follow:
> Class Definition for Class 527 - SYNTHETIC RESINS OR NATURAL RUBBERS ...
> D. a lignin, tannin, or derivative thereof, E. a reactant which is coal or bituminous material, an extract or derivative thereof, or a fatty still residue,
> http://www.uspto.gov/.../defs527.htm - Cached
> Class Schedule for Class 536 ORGANIC COMPOUNDS -- PART OF THE CLASS ...
> This Class 536 is considered to be an integral part of Class 260 (see the Class 260 ... Novobiocin or derivative
> http://www.uspto.gov/.../sched536.htm - Cached
> Class Schedule for Class 424 DRUG, BIO-AFFECTING AND BODY TREATING ...
> Attached to carbohydrate compound; derivative thereof (e.g., DNA, nucleotide, nucleoside, sugar, starch, tannin, saccharide, polysaccharide, cellulose, O-, N- and S-glycoside ...
> http://www.uspto.gov/.../sched424.htm - Cached
> Class Schedule for Class 527 SYNTHETIC RESINS OR NATURAL RUBBERS ...
> With di- or higher ester of polycarboxylic acid; or with polycarboxylic acid or derivative and a compound containing two or more hydroxyl groups or salts thereof as reactants
> http://www.uspto.gov/.../sched527.htm - Cached
> Class Schedule for Class 507 EARTH BORING, WELL TREATING, AND OIL ...

Organic component is carbohydrate or derivative thereof (e.g., sugar or gum, such as galactomannan, xanthan, etc.) or carboxylic acid ester of an alcohol which has five or more ...
http://www.uspto.gov/.../sched507.htm - Cached
Class Definition for Class 51 - ABRASIVE TOOL MAKING PROCESS ...
Cellulose or derivative thereof: This subclass is indented under subclass 302. Subject matter including (a) a process involving the use of cellulose or a derivative thereof or (b ...
http://www.uspto.gov/.../defs051.htm - Cached
Class Schedule for Class 525 SYNTHETIC RESINS OR NATURAL RUBBERS ...
Solid polymer derived from a lactam; from an amino carboxylic acid or derivative; from a polyamine and a polycarboxylic acid or derivative
http://www.uspto.gov/.../sched525.htm - Cached
Class Schedule for Class 528 SYNTHETIC RESINS OR NATURAL RUBBERS ...
Reactant which contains at least two -C-C(=X)-X-C groups has been derived from only a dicarboxylic acid or derivative and only a dihydric alcohol or alcoholate derivative
http://www.uspto.gov/.../sched528.htm - Cached
Class Schedule for Class 521 SYNTHETIC RESINS OR NATURAL RUBBERS ...
At least one polymer is derived from a polycarboxylic acid or derivative and a polyol or wherein the polymer-forming system containing the same type of reactants
http://www.uspto.gov/.../sched521.htm - Cached
Class Definition for Class 536 - ORGANIC COMPOUNDS -- PART OF THE ...
Erythromycin or derivative (e.g., oleandomycin, etc.): This subclass is indented under subclass 7.1. Compounds which have the following structure and derivatives thereof wherein ...

Furthermore, as pointed out in the January 21, 2011 Amendment After Final Rejection Under 37 CFR 1.116, the plain, ordinary, dictionary meaning of "derivative" (Webster's New Collegiate Dictionary G& C Merriam Co., Publishers, Springfield, MA page. 223, 1956, a copy of which was submitted with a January 24, 2011 Letter and is attached with Appellant's Evidence Appendix) defines a derivative in chemistry as "A substance so related to another substance by modification or partial substitution as to be regarded as derived from it, even when not obtainable from it in practice; thus, the amino compounds are derivatives of ammonia." It is well established that ordinary dictionary

meanings may be used to interpret claim terms. One of ordinary skill in the art would know structures of polyvinyl acetate derivatives which are recognizable or regarded as derived from polyvinyl acetate, and would have understood the inventor to be in possession of the claimed invention at the time of filing. Furthermore, the term is employed in the context of examples of hydrophobic agents which may used to control the rate of release of encapsulants. See page 13 lines 3-16. Appellant need not provide examples of examples to satisfy the written description requirement.

It was indicated in the March 1, 2011 Advisory Action that the rejection was being maintained because Appellant provides no other characteristics (other than the compounds are hydrophobic) or structure to indicate to one of skill in the art as to what structures are encompassed by the derivative, or the extent to which the polymer may be modified before it is no longer considered a derivative of polyvinyl acetate. According to the Advisory Action, one of ordinary skill in the art would not be able to immediately envision what compounds are encompassed by the recitation of polyvinyl acetate "derivatives." In the June 30, 2011 Advisory Action the Examiner indicates that no examples of what compounds would encompass a hydrophobic polyvinyl derivative or groups that modify the structure to render the polyvinyl acetate derivative hydrophobic are provided in Appellant's specification. However, those skilled in the art know which functional groups may be employed to modify a polymer to make it hydrophobic. Moreover, one of ordinary skill in the art would be able to immediately envision at least known polyvinyl acetate derivatives which are hydrophobic. The structure of polyvinyl

acetate is known and the structure of numerous polyvinyl acetate derivatives are known to those skilled in the art. Indeed, Newton et al, cited by the Examiner, employs the term "derivatives" in connection with the broader phrase natural polymers and derivatives thereof, in the paragraph bridging columns 8 and 9, and col. 9 lines 18-21, and Wittwer et al, previously cited, employs the term "derivatives" in connection with the term starch (USP 4,738,724 at col. 7 line 67 to col. 8 line 24). According to Webster's dictionary a derivative is a substance so related to another substance by modification or partial substitution as to be regarded as derived from it, even when not obtainable from it in practice, so clearly compounds so related to polyvinyl acetate by modification or partial substitution as to be regarded as derived from it could be envisioned by those skilled in the art.

Appellant submits that one ordinarily skilled in the art would readily understand how to make and use the claimed encapsulated products using the claimed polyvinyl acetate derivatives, even without express disclosure of any species of polyvinyl acetate derivatives in Appellant's disclosure because, *inter alia*, specific examples are known to those skilled in the art and Appellant discloses and claims their function.

C. Claims 31, 59, 108 And 109 Are Not Properly Rejected Under 35 U.S.C. 112, Second Paragraph, As Being Indefinite For Failing To Particularly Point Out And Distinctly Claim The Subject Matter Which Applicant Regards As The Invention.

In the March 1, 2011 Advisory Action Appellant's arguments presented in the January 21, 2011 response were indicated as persuasive regarding the term "modified

starch" and the rejection is withdrawn as to that term. However, regarding the derivatives of polyvinyl acetate it was indicated in the March 1, 2011 Advisory Action that the rejection was being maintained. The June 30, 2011 Advisory Action is consistent in only addressing the recitation of a polyvinyl acetate derivative.

The rejection of claims 31, 59, 108, and 109 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because of use of the term "derivative" is untenable for reasons as given above with respect to the rejection under the first paragraph of 35 U.S.C. 112.

The Examiner maintains that it is unclear how far one can deviate from the parent compound without the derivative being so far removed therefrom so as to be a completely different compound. As discussed above, the plain, ordinary, dictionary meaning of "derivative" (Webster's New Collegiate Dictionary G& C Merriam Co., Publishers, Springfield, MA page. 223, 1956) defines a derivative in chemistry as "A substance so related to another substance by modification or partial substitution as to be regarded as derived from it, even when not obtainable from it in practice; thus, the amino compounds are derivatives of ammonia." It is well established that ordinary dictionary meanings may be used to interpret claim terms. One of ordinary skill in the art would have understood a structure related to the structure of polyvinyl acetate. One of ordinary skill would have understood the meaning of "derivative" in the context of the term "polyvinyl acetate derivative," and in the context of the specification and claims alone (which recite

its hydrophobic agent function), or with the ordinary dictionary meaning of a "derivative".

The term is employed in the context of examples of hydrophobic agents which may used to control the rate of release of encapsulants. See page 13 lines 3-16. Appellant need not provide examples of examples to satisfy the second paragraph of 35 U.S.C. 112. Additionally, Newton et al, cited by the Examiner, employs the term "derivatives" in connection with the broader phrase natural polymers and derivatives thereof, in the paragraph bridging columns 8 and 9, and col. 9 lines 18-21, and Wittwer et al, previously cited, employs the term "derivatives" in connection with the term starch (USP 4,738,724 at col. 7 line 67 to col. 8 line 24). Also, discussed above, the term "derivative" is well known to those skilled in the art as exemplified by the extensive use of the term in the USPTO class definitions. It is submitted that those skilled in the art would know the meaning of polyvinyl acetate derivatives, and Appellant can claim as broadly as the art permits.

D. Claims 25-31, 34, 35, 37-40, 46, 50, 52-59, 61, 62, 64-67, 73, 75, 79, 81-83, 85, 91-93, 95-97, 101, 103, 105, 108, and 109 are not properly rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (U.S. Patent No. 4,938,967) in view of Eden et al (U.S. Patent No. 4,755,397).

Neither Newton et al nor Eden et al, taken alone or in combination teach or suggest the use of a plasticized mass comprising starch which is not substantially destructured or dextrinized, as claimed in independent claims 25, 27, 52, 54, and 83, and

their dependent claims. Even if the references were properly combinable, Appellant's claimed products would not be obtained or rendered obvious.

The Examiner employs Newton et al as teaching pharmaceutical compositions. Newton et al employs a weighting agent to increase density beyond normal levels to thereby increase release time. The weighting agent generally is employed in an amount of at least 50% by weight of the unit, and generally has a density of at least 2.5 g/ml. The weighting agent may be a powder such as barium sulphate, ferric oxide, ferrum redactum, titanium dioxide and aluminum oxide or hydroxide, calcium carbonate, barium phosphate, bismuth phosphate, calcium aluminosilicate, zirconium silicate, calcium phosphate, silicon carbide, and magnesium carbonate. See col. 4 lines 33-52, col. 5 lines 7-9, and col. 9 line 43 to col. 10 line 1.

Newton et al discloses the use of a conventional matrix binder which may be a synthetic polymer or natural polymer or derivative such as starch or preferably cellulose or its derivatives. A known gastric controlled release binder may also be employed such as hydrophobic acrylic polymers or cellulose derivatives, vinyl polymers and other high molecular weight natural polymer derivatives or synthetic polymers. See col. 8 line 61 to col. 9 line 36. Each unit may comprise a homogeneous or non-homogeneous blend of the active ingredient and the weighting agent and any matrix binder component. For instance each unit may have a core of weighting agent covered by a shell of active ingredient or vice versa or it may be formed of a blend of the active ingredient and the weighting agent. See col. 10 lines 58-64. The preferred method for forming the pellets or other

units is to make a mixture of the weighting agent and the active ingredient and matrix binder and then to form the mixture into the units. Generally some water is added to the mixture to aid pelletization. See col. 11 lines 34-44.

In the March 1, 2011 Advisory Action, the Examiner admits that "Newton does not teach a plasticized matrix and asserts that the secondary reference, Eden, discloses a plasticized matrix and gives motivation as to why one of ordinary skill in the art would want to use a plasticized starch in the compositions of Newton." Now, in the June 30, 2011 Advisory Action, the Examiner notes, for the first time, that the claims recite "a plasticized mass comprising starch" and "do not recite a plasticized starch," and "the compositions of Newton may comprise plasticizers," it is now asserted that "Newton would encompass a plasticized mass comprising starch." However, the term "plasticized mass comprising starch" means that the plasticized mass contains plasticized starch and may contain other plasticizable matrix materials. In this regard, the claims recite a plasticized matrix material, and as recited in independent claims 25 and 27, the plasticized mass includes about 40% or more by weight of at least one matrix material which is plasticized. Independent claims 52, 54, and 83 recite a plasticized matrix material comprising starch which is not substantially destructurized or dextrinized, which means that the plasticized matrix material contains plasticized starch and may contain other plasticizable matrix materials. See also, page 23 line 30 which recites "plasticized starch matrix."

Regarding the Examiner's assertion in the June 30, 2011 Advisory Action that the presence of a plasticizer in the composition of Newton et al, and in the composition of Eden et al would indicate that the compositions could be interpreted as plasticized masses, as discussed in the January 21, 2011 Amendment After Final Rejection at page 19, just because a plasticizer may be present does not mean that a matrix material such as starch is plasticized. As disclosed in the present specification, a sufficient amount of water and high temperatures are needed to gelatinize starch and produce a plasticized matrix from starch. See, for example, page 7 lines 4-15, page 8 line 22 to page 9 line 5, and page 22 line 12 to page 23 line 3. Mere mixing of starch and water does not produce a plasticized mass as claimed. As demonstrated by the data shown in Table 1 and FIG. 6, in Comparative Example 2 (M1) at pages 39-41, pure starch does not present a sufficient matrix for encapsulation, because the time to release 100% of the encapsulant is too short.

Also, contrary to the Examiner's assertion in the June 30, 2011 Advisory Action, Appellant's specification clearly discloses what is encompassed by "a plasticized matrix" and "not substantially destructured or dextrinized" and neither Eden et al nor the other cited references teach or suggest a plasticized matrix material comprising starch which is not substantially destructured or dextrinized. Also, as argued in the August 18, 2010 Amendment regarding the subsequently withdrawn 35 U.S.C. 112, second paragraph rejection of the claims regarding the term "substantially", guidance to avoid substantial dextrinizing and destructurizing of starch is provided in the instant specification, for

example, by way of extrusion operating conditions, such as temperature, pressure, shear, residence time, and degree of starch gelatinization.

The Eden et al reference does not disclose production of a plasticized matrix, and the Eden et al process does not inherently produce a plasticized starch because, *inter alia*, as disclosed by the reference, Eden et al desires and obtains a cooked starch which is highly retrograded, or highly crystalline, and is not soluble in water, whereas a plasticized starch obtained by heating with low shear in an extruder to obtain a dough is amorphous or glassy. See Eden et al col. 1 lines 25-37 which states:

> In accordance with the present invention, the materials to be encapsulated are combined with a high temperature-stabilized dispersion of starch in a saturated salt solution. The temperature-stabilized starch dispersion acts as a protective colloid, encasing the material to be encapsulated. Upon subsequent rapid cooling of this mixture the starch polymer chains collapse upon themselves, forming a highly crystalline particulate-form matrix encapsulating the core material. In the resultant precipitate, the material being encapsulated is evenly distributed throughout the starch matrix. However, the starch in the resultant encapsulated products is highly retrograded, thus forming a water insensitive product. (Emphases Added.)

However, as disclosed in the present specification at, for example, the paragraph bridging pages 6 and 7, the paragraph bridging pages 7 and 8, the paragraph bridging pages 12 and 13, the paragraph bridging pages 22 and 23 to page 23 second full paragraph, and the first full paragraph on page 26, low shear mixing, low temperature and plasticizer amounts, and extrusion residence time, screw speeds, and screw configuration

are employed to achieve plasticization without substantial destructurization or dextrinization of the starch:

> ...The controlled release or delayed release composition may be produced without substantial expansion of the matrix material to thereby avoid production of a low density product which prematurely or too rapidly releases the encapsulant or the embedded component. The products may be produced using low shear mixing to avoid decomposition of the matrix material and encapsulant or active component. However, even though low shear mixing is utilized, substantial plasticization of the matrix material and at least substantially uniform distribution of the active component are achieved. (Emphases Added, paragraph bridging pages 6 and 7)
>
> ....The matrix material is plasticized upon heating to form a melt. The active component is admixed with the melt without substantially deleteriously affecting or decomposing the encapsulant or the matrix material. The active component is admixed with the plasticized matrix material at low temperatures and under low shear mixing conditions to thereby avoid substantial destruction of or volatilization of active components. Additionally, high water contents may be employed so as to substantially reduce viscosity and facilitate substantial gelatinization of the starch without substantially destroying the starch molecules. (Emphases Added, paragraph bridging pages 7 and 8.)
>
> The plasticizer or softener which may be used to lower the melt temperature or glass transition temperature (T_g) of the matrix material and facilitate plastification is preferably water but may be an aqueous-based composition such as a sugar solution, alcohol, sorbitol, polyethylene glycol, polypropylene glycol, silicone, hexanol, pentanol, dimethylsulfoxide (DMSO), hexane, or an oil. The amount of plasticizer, such as water, should be sufficient to substantially reduce the melt or glass transition temperature of the plasticizable material such as starch so that it may be admixed with the other ingredients at a sufficiently low temperature and under sufficiently low shear conditions so as to avoid substantial mechanical or thermal destruction of the plasticizable material or matrix material. (Emphases Added, paragraph bridging pages 12 and 13.)
>
> In accordance with the method of the present invention, the matrix material or plasticizable material and the plasticizer are admixed and heated to plasticize and melt the matrix material under low shear mixing conditions without substantially destroying or decomposing the matrix material. In preferred embodiments, the matrix material and the

plasticizer may be added to the upstream end of an extruder, mixed and heated above the melt temperature of the plasticizable material or above the gelatinization temperature of starch while mixing and conveying these ingredients inside the extruder. In embodiments where starch is used as a matrix material, the starch is at least partially gelatinized without substantially destructurizing and dextrinizing the starch. The degree of gelatinization may, for example, be at least about 75%, for example, at least about 90%, or essentially completely gelatinized. In embodiments of the invention, to achieve at least substantial gelatinization of starch, the starch and plasticizer (preferably water) admixture may be maintained at a temperature of the blend of at least about 100°C, preferably from about 120°C to about 150°C, for example, from about 125°C to about 140°C, for a period of time of at least about 3 l/d preferably about 5 to 7 l/d of extruder length. For example, for starches having an amylose content of more than about 25%, for example about 50% to about 70%, it may be necessary to maintain a product temperature inside the extruder of about 125°C for a sufficient amount of time, for example for about 4 l/d, preferably about 7 to 8 l/d of extruder length at a low screw rotational rate of about 150 to about 200 rpm using medium pitch screw elements to assure at least substantial gelatinization of the starch.

In embodiments of the invention, the pressure maintained within the cooking section or gelatinization section or plastification zone may be between about 5 to 100 bars, preferably between about 10 and 35 bars.

An overall quantitative measure of the shear used inside the extruder during the cooking process is the specific mechanical energy input. In embodiments of the present invention, the specific mechanical input during cooking may be below about 150 Wh/kg, preferably below about 100 Wh/kg, and most preferably below about 50 Wh/kg. (Emphases Added, paragraph bridging pages 22 and 23 to page 23 second full paragraph.)

The admixing of the added active ingredients or encapsulants inside the extruder may be accomplished by using an appropriate extrusion screw configuration for achieving low shear mixing. For example, a combination of alternating small pitch conveying elements with distributive mixing elements, that are staggered at an angle to each other for providing axially oriented leakage flow inside the extruder barrel may be employed. The combination of alternating conveying elements with distributive mixing elements cause the material flow to be continuously interrupted without shearing of the mass thus resulting in mixing of the material at low mechanical energy input. (Emphases Added, first full paragraph on page 26.)

Eden et al does not disclose that the starch is plasticized and the Examiner has not provided any rationale as to why the starch of Eden et al is plasticized, or pointed to disclosure in the reference which supports the position taken in the March 1, 2011 Advisory Action or the June 30, 2011 Advisory Action that the starch is plasticized.

For inherency to be present the Examiner has the burden of showing that the result indicated by the Examiner is the necessary result, and not merely a possible result. In re Oelrich, 212 U.S.P.Q. 323 (CCPA 1981); Ex parte Keith et al., 154 U.S.P.Q. 320 (POBA 1966). For example, the fact that a prior art article may inherently have the characteristics of the claimed product is not sufficient. Ex parte Skinner, 2 U.S.P.Q.2d 1788 (BPAI 1986).

As the Board of Patent Appeals and Interferences states in Ex parte Levy, 17 U.S.P.Q.2d 1461, 1463:

> However, the initial burden of establishing a prima facie basis to deny patentability to a claimed invention rests upon the examiner. In re Piasecki, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984). In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986); W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); In re Oelrich , 666 F.2d 578, 212 USPQ 323 (CCPA 1981); In re Wilding, 535 F.2d 631, 190 USPQ 59 (CCPA 1976); Hansgirg v. Kemmer, 102 F.2d 212, 40 USPQ 665 (CCPA 1939).in order for inherency to be present it must be a necessary result, and not merely a possible results. Ex parte Keith and Turnquest, 154 U.S.P.Q. 320 (B.O.A. 1966).

None of the references, taken alone or in combination teach or suggest the same steps as employed by Appellant, and the rejection does not establish that the method for producing the composition of the references would either explicitly or inherently produce a product as claimed by Appellant.

Even if Eden et al employs temperatures which may be employed in the production of Appellant's claimed process, that does not mean that the starch obtained by Eden et al is inherently or necessarily plasticized, or not substantially destructured or dextrinized. The highly retrograded starch of Eden et al is produced by a jet cooker using steam and is totally destructured, with the granular structure of the starch granules being totally destroyed, whereas Appellant employs low shear extrusion as explained above. It is believed that in the Eden et al process, the starch molecules in the starch granules are separated from each other and then crystallized, with the encapsulant entrapped between the crystallized starch molecules. This is evidenced by Eden et al's disclosure that the starch molecules collapse on themselves forming a highly crystalline particulate-form matrix encapsulating the core material as disclosed at col. 1 lines 30-37. Also, according to Eden et al, col. 4 lines 5-9, the starch is cooked even though a large amount of salt is present as a gelatinization inhibitor, further evidencing that total destructuring occurs.

In the June 30, 2011 Advisory Action, the Examiner asserts that it is reasonable to conclude that portions of the starch are amorphous because the reference discloses "highly crystalline" and not that the starch is fully crystalline, and thus the reference meets the limitation of a starch not substantially destructured or dextrinized. However,

full crystallinity is not required for a "highly crystalline" material to be substantially destructured or dextrinized.

Further, as disclosed at col. 2 lines 34-47 and col. 4 lines 22-24 Eden et al employs a large amount of salt, which it is believed, is added to rapidly precipitate the starch molecules as small particles, such as only 5-7 microns in diameter, rather than to form a dough or plasticized mass. See col. 1 lines 50-54, col. 2 lines 52-56, and col. 4 lines 16-26. However, Newton et al discloses it is critical to have particle sizes of at least 2 mm (2000 microns) at col. 4 lines 63-65, which is much larger than the particle size obtained by Eden et al's process.

> The pharmaceutical dosage form must have a dimension of above about 2 mm since dosages smaller than this are inconvenient and ineffective. (Emphases Added, Eden et al col. 4, lines 63-65.)

The Eden et al process produces particles which are too small to employ effectively in the Newton et al product which requires a critically larger particle size for effectiveness, so there is no reason to use Eden's composition or method for the Newton et al composition. In the June 30, 2011 Advisory Action it is alleged that one ordinarily skilled in the art would adjust the shear and solids levels of Eden et al to arrive at the particle size disclosed by Newton et al. However, there is no reason to do so, there is no guidance as to how to increase the particle size of Eden et al by several orders of magnitude from only 5-7 microns to the 2,000 microns required by Newton et al.

A dough or plasticized mass is not obtained and the starch is completely destructured in the process and product of Eden et al. However, in Appellant's claimed

product, the starch molecules are not substantially destructured. The encapsulation in Appellant's product is not on a molecular basis, between crystallized starch molecules, but rather in a plasticized, glassy mass formed from a dough that has been dried, where the starch is not substantially destructured.

During an April 5, 2011 telephonic interview, and in the June 30, 2011 Advisory Action, the Examiner pointed out that the claims do not exclude some degree of destructuring and dextrinization of the starches. However, the claims exclude the total or substantial destructurization which is obtained by the Eden et al process. A substantial portion of the starch in the products of the present invention does not have to be gelatinized at all, and at least a portion of the starch does not have to be gelatinized and can be in its native, granular form, which is distinctly different from the Eden product where no granular starch is present in the treated product. In the Eden et al product almost all starch molecules are collapsed molecules and are precipitated in a highly crystalline form, whereas in the plasticized mass of Appellant, that portion of starch in the matrix that actually has been cooked, is in the amorphous or glassy, and essentially non-crystalline form.

During the April 5, 2011 interview, and in the June 30, 2011 Advisory Action, the Examiners questioned as to what was meant by plasticized. As disclosed at page 9, first full paragraph, of the present application, the plasticized starch forms a dough, and some amylose and amylopectin may exude from the starch granules so that the granules stick together to form a dough, but the starch granules are not totally destructured so that the

molecules collapse on each other and form a highly crystalline starch as in the Eden et al process and product.

Newton et al alone or combination with Eden et al does not teach or suggest use of a plasticized mass comprising starch which is not substantially destructured or dextrinized, and there is no reason to do so.

Claims 34 and 61

As discussed during the April 5, 2011 interview, the rejection of claims 34 and 61 is improper for the additional reason that they recite a density of 800 g/liter to 1500 g/liter (0.8 to 1.5 g/ml) whereas according to Newton et al at col. 5 lines 7-9, a higher density of above about 2 g/ml (2000 g/liter) is critical to Newton et al for achieving an increased residence time in the stomach:

> For a useful increase in human gastric residence time to occur, it is essential that the density is above about 2 g/ml. (Emphasis Added, Newton et al at col. 5 lines 7-9.)

At the interview, the Examiners asked whether Appellant's recited upper limit of "about" 1.5 g/ml would overlap with the Newton et al critical amount of above about 2 g/ml. However, the amounts would not overlap because Newton et al distinguishes a density of "about 1.0 to 1.5 g/ml" as being conventional at col. 2 lines 11-12 whereas it is taught that above about 2 g/ml is critical to the Newton et al product.

Even if the references were properly combinable, Appellant's claimed products would not be obtained or rendered obvious.

E. Claims 42, 69, 70, 84, and 108-110 are not properly rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (U.S. Patent No. 4,938,967) in view of Eden et al (U.S. Patent No. 4,755,397) in further view of Jane et al (U.S. Patent No. 5,397,834.

In the November 23, 2010 Final Rejection, the Examiner admits that Newton et al. and Eden et al differ from the instant claims insofar as they do not disclose the wheat used as a starch source is durum wheat. The Examiner points out that Jane et al discloses biodegradable thermoplastic components made of the reaction of a starch aldehyde with protein, that suitable starches include those derived from durum wheat, and that the reference differs from the instant claims in so far as it does not disclose the thermoplastic compositions are formulated into discrete particles comprising an active agent. It is alleged that it would have been obvious to one of ordinary skill in the art to have used wheat durum as the wheat in the compositions of the combined teachings of Newton et al and Eden et al motivated by the desire to use a wheat comprising starch suitable for making thermoplastic compositions as disclosed by Jane et al.

However, neither Newton et al nor Eden et al disclose the use of wheat flour, which contains starch as well as other components, and which is different from pure or raw starch, and there is no reason to employ a wheat flour instead of a starch in the products of Newton et al or Eden et al. Plasticized wheat flour and plasticized durum wheat have different compositions, such as proteins, and different release properties from those of a starch of Newton et al or Eden et al, as demonstrated in Examples 4 to 8 and Comparative Example 2 at pages 39-41 of the present specification and FIG. 6.

Jane et al does not cure the deficiencies in the disclosures of Newton et al and Eden et al discussed above, and even if it were obvious to combine the teachings of Newton et al, Eden et al, and Jane et al, Appellant's claimed invention would not be obtained nor rendered obvious. The Examiner maintains that Newton et al and Eden et al differ from the instant claims insofar as they do not disclose the wheat used as a starch source is durum wheat. As discussed above, Newton et al and Eden et al, even if properly combinable, do not teach or suggest particles where for each particle an encapsulant is dispersed throughout a plasticized mass comprising starch which is not substantially destructured or dextrinized. Even if it were obvious to employ a starch derived from durum wheat in the product of Newton et al, which it is not, Appellant's claimed products would not be obtained nor rendered obvious.

Moreover, a starch which is derived from durum wheat is not the same as durum wheat which has different matrix forming properties and different release properties. Durum wheat contains gluten which forms a plasticizable starch-protein matrix, and as disclosed in the present invention, heating or cooking of durum wheat to gelatinize starch is not required. See, for example, page 23, lines 12-14. Use of starch derived from durum wheat would not include the gluten and would result in a different matrix and different release properties.

In the March 1, 2011 Advisory Action, and in the June 30, 2011 Advisory Action, the Examiner maintains that Jane et al discloses the use of starch from durum wheat and Eden et al discloses the starch may be from wheat. It is asserted that the references do

not exclude using starch that has not been isolated from its source and therefore it would have been obvious to use durum wheat because it is a source of starch. However, even if a reference does not exclude a component, that is not a reason for using the component. Moreover, Jane et al discloses biodegradable thermoplastic components made of the reaction of a starch aldehyde with protein, which according to Jane et al has a very different texture, tensile strength, elongation, and water resistance compared to articles made from native starch and protein. See abstract and col. 1 lines 41-58. Even if Jane et al discloses that suitable starches include those derived from durum wheat, that is no reason to employ durum wheat in the products of Newton et al and Eden et al. Jane et al clearly desires aldehyde starch, not the raw material starch nor its source, such as durum wheat as a reactant for reaction with the protein to make the thermoplastic. See col. 3 line 36 to col. 4 line 50. Durum wheat contains a high content of gluten which could interfere or compete with the desired reaction of Jane et al for making the aldehyde starch. In the March 1, 2011 Advisory Action, the Examiner asserts that heating the wheat would not appear to alter the properties to make it unsuitable for use in the compositions of the combination of Newton et al and Eden et al . However, the jet cooking employed by Eden et al could denature the protein of durum wheat, as well as completely destructure the starch as discussed above.

Jane et al does not cure the deficiencies in the disclosures of Newton et al and Eden et al discussed above and even if it were obvious to combine the teachings of

Newton et al, Eden et al, and Jane et al, Appellant's claimed invention would not be obtained nor rendered obvious.

VIII. CONCLUSION

At least in view of the above, Appellant respectfully requests that the Examiner's decision to reject the claims on appeal be reversed. In this regard, if there are any questions about this application, any representative of the U.S. Patent and Trademark Office is invited to contact the undersigned at the telephone number listed below.

Respectfully Submitted,
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IX. CLAIMS APPENDIX

25. An encapsulated product comprising discrete, solid particles having a substantially uniform shape and a diameter of up to about 10 mm,
wherein each particle comprises:

an encapsulant dispersed throughout a plasticized mass comprising starch which is not substantially destructured or dextrinized, and at least one component for controlling the rate of release of the encapsulant,

wherein said encapsulant is at least one pharmaceutical component, neutraceutical component, nutritional component, fragrance component, or biologically active component,

wherein said plasticized mass comprises about 40% or more by weight of at least one matrix material, based on the weight of the final product, and at least one plasticizer comprising water,

wherein the encapsulant and plasticized matrix material form an at least substantially homogeneous mixture, and

wherein the amount of said encapsulant is from about 1% by weight to about 85% by weight, based upon the weight of the matrix material.

26. An encapsulated product according to claim 25 wherein said plasticized matrix material comprises an at least partially gelatinized starch, which starch is not substantially destructured or dextrinized.

27. An encapsulated product comprising discrete, solid particles having a substantially uniform shape and a diameter of up to about 10 mm,
wherein each particle comprises:

an encapsulant dispersed throughout a plasticized mass comprising starch which is not substantially destructured or dextrinized, and at least one component for controlling the rate of release of the encapsulant,

wherein said encapsulant is at least one pharmaceutical component, neutraceutical component, nutritional component, fragrance component, or biologically active component,

wherein said plasticized mass comprises about 40% or more by weight of at least one matrix material, based on the weight of the final product, and at least one plasticizer,

wherein the encapsulant and plasticized matrix material form an at least substantially homogeneous mixture,

wherein the amount of said encapsulant is from about 1% by weight to about 85% by weight, based upon the weight of the matrix material, and

wherein said encapsulant is coated with a film-forming material prior to dispersion within said plasticized mass.

28. An encapsulated product according to claim 25 wherein said particles are in the form of a tablet, or a pellet.

29. An encapsulated product according to claim 28 wherein said particles are coated with a film-forming material.

30. An encapsulated product according to claim 25 wherein said at least one release-rate controlling component is a hydrophobic component.

31. An encapsulated product according to claim 30 wherein said hydrophobic component is at least one member selected from the group consisting of fats, oils, waxes, fatty acids, emulsifiers, polyolefins, paraffin, polyvinyl acetate and derivatives thereof, and modified starches.

34. An encapsulated product according to claim 25 which has a specific density of from about 800 g/liter to about 1500 g/liter.

35. An encapsulated product according to claim 25 wherein the length-to-diameter ratio of said particles is from about 0.1 to about 10.

37. An encapsulated product according to claim 25 wherein said particles have a substantially non-expanded, substantially non-cellular structure.

38. An encapsulated product according to claim 25 wherein said encapsulant is released in an aqueous or gastric juice environment in an amount of no more than from about 10% in about 1 hour to no less than about 90% in about 24 hours.

39. An encapsulated product according to claim 25 wherein:

the amount of the matrix material is from about 60% by weight to about 95% by weight, based upon the weight of the final product, and

the amount of said at least one component used to control the rate of release of the encapsulant is from about 5% by weight to about 50% by weight, based upon the weight of the matrix material.

40. An encapsulated product according to claim 39 wherein said particles have a diameter of from about 0.5 mm to about 5 mm and a length-to-diameter ratio of about 0.5 to about 2.

42. An encapsulated product according to claim 25 wherein said plasticized matrix comprises durum wheat or semolina.

46. An encapsulated product according to claim 25 wherein said encapsulant is at least one member selected from the group consisting of antioxidants, phytochemicals, hormones, microorganisms, prebiotics, probiotics, enzymes, formulations containing

zidovudine, macromolecular polypeptides, aromatic nitro and nitroso compounds and their metabolites useful as anti-viral and anti-tumor agents, HIV protease inhibitors, antibiotics, viruses, steroids, oligopeptides, dipeptides, amino acids, fragrance components, adenosine derivatives, sulfated tannins, monoclonal antibodies, and metal complexes of water-soluble texathyrin.

50. An encapsulated product according to claim 25 wherein said plasticized matrix material further comprises at least one member selected from the group consisting of cyclodextrins, dextrins, monosaccharides, disaccharides, polyvinylpyrrolidone, copolymers of N-vinylpyrrolidone and vinyl acetate, polyvinyl alcohol, cellulose esters, cellulose ethers, and polyethylene glycol.

52. An encapsulated product comprising:

discrete, solid particles having a substantially uniform shape wherein each particle comprises:

a plasticized matrix material in an amount of about 40% or more by weight, based on the weight of the final encapsulated product, wherein said plasticized matrix material comprises starch which is not substantially destructured or dextrinized,

an encapsulant dispersed throughout the plasticized matrix material, and

at least one component for controlling the rate of release of the encapsulant,

wherein said encapsulant comprises at least one pharmaceutical component, neutraceutical component, nutritional component, fragrance component, or biologically active component,

wherein said matrix material comprises at least one member selected from the group consisting of durum wheat, semolina, wheat flour, wheat gluten, soy protein, hydrocolloids, casein, and gelatin, and at least one plasticizer comprising water,

wherein the encapsulant and plasticized matrix material form an at least substantially homogeneous mixture, and

wherein the amount of said encapsulant is from about 1% by weight to about 85% by weight, based upon the weight of the matrix material.

53. An encapsulated product according to claim 52 wherein said plasticized matrix material comprises an at least partially gelatinized starch, which starch is not substantially destructurized or dextrinized.

54. An encapsulated product comprising:

discrete, solid particles having a substantially uniform shape wherein each particle comprises:

a plasticized matrix material in an amount of about 40% or more by weight, based on the weight of the final encapsulated product, wherein said plasticized matrix material comprises starch which is not substantially destructurized or dextrinized,

an encapsulant dispersed throughout the plasticized matrix material, and

at least one component for controlling the rate of release of the encapsulant,

wherein said encapsulant comprises at least one pharmaceutical component, neutraceutical component, nutritional component, fragrance component, or biologically active component,

wherein said matrix material comprises at least one member selected from the group consisting of durum wheat, semolina, wheat flour, wheat gluten, soy protein, hydrocolloids, casein, and gelatin, and at least one plasticizer,

wherein the encapsulant and plasticized matrix material form an at least substantially homogeneous mixture,

wherein the amount of said encapsulant is from about 1% by weight to about 85% by weight, based upon the weight of the matrix material, and

wherein said encapsulant is coated with a film-forming material prior to dispersion within said plasticized mass.

55. An encapsulated product according to claim 52 wherein said particles are in the form of a tablet, or a pellet.

56. An encapsulated product according to claim 52 wherein said particles are spherical.

57. An encapsulated product according to claim 55 wherein said particles are coated with a film-forming material.

58. An encapsulated product according to claim 52 wherein said at least one release-rate controlling component is a hydrophobic component.

59. An encapsulated product according to claim 58 wherein said hydrophobic component is at least one member selected from the group consisting of fats, oils, waxes, fatty acids, emulsifiers, polyolefins, paraffin, polyvinyl acetate and derivatives thereof, and modified starches.

61. An encapsulated product according to claim 52 which has a specific density of from about 800 g/liter to about 1500 g/liter.

62. An encapsulated product according to claim 52 wherein the length-to-diameter of said particles is from about 0.1 to about 10.

64. An encapsulated product according to claim 52 wherein said particles have a substantially non-expanded, substantially non-cellular structure.

65. An encapsulated product according to claim 52 wherein said encapsulant is released in an aqueous or gastric juice environment in an amount of no more than from about 10% in about 1 hour to no less than about 90% in about 24 hours.

66. An encapsulated product according to claim 52 wherein the amount of said at least one component for controlling the rate of release of the encapsulant is up to about 70% by weight, based on the weight of the matrix material.

67. An encapsulated product according to claim 52 wherein said particles have a diameter of from about 0.5 mm to about 5 mm and a length-to-diameter ratio of about 0.5 to about 2.

69. An encapsulated product according to claim 52 wherein said matrix material comprises at least one member selected from the group consisting of durum wheat, semolina, wheat flour, wheat gluten, and soy protein.

70. An encapsulated product according to claim 52 wherein said matrix material comprises at least one member selected from the group consisting of durum wheat and semolina.

73. An encapsulated product according to claim 52 wherein said discrete, solid particles have a diameter of up to about 10 mm.

75. An encapsulated product according to claim 52 wherein said encapsulant is at least one member selected from the group consisting of antioxidants, phytochemicals, hormones, microorganisms, prebiotics, probiotics, enzymes, formulations containing zidovudine, macromolecular polypeptides, aromatic nitro and nitroso compounds and their metabolites useful as anti-viral and anti-tumor agents, HIV protease inhibitors,

antibiotics, viruses, steroids, oligopeptides, dipeptides, amino acids, fragrance components, adenosine derivatives, sulfated tannins, monoclonal antibodies, and metal complexes of water-soluble texathyrin.

79. An encapsulated product according to claim 52 wherein said plasticized matrix material further comprises at least one member selected from the group consisting of cyclodextrins, dextrins, monosaccharides, disaccharides, polyvinylpyrrolidone, copolymers of N-vinylpyrrolidone and vinyl acetate, polyvinyl alcohol, cellulose esters, cellulose ethers, and polyethylene glycol.

81. (Previously presented) An encapsulated product according to claim 52 wherein:

the amount of the matrix material is from about 60% by weight to about 95% by weight, based upon the weight of the final product, and

the amount of said at least one component used to control the rate of release of the encapsulant is from about 5% by weight to about 50% by weight, based upon the weight of the matrix material.

82. An encapsulated product according to claim 52 wherein said encapsulant comprises at least one member selected from the group consisting of enzymes and microorganisms.

83. An encapsulated product comprising discrete, solid particles having a substantially uniform shape wherein each particle comprises:

an encapsulant dispersed throughout a plasticized matrix material comprising starch which is not substantially destructurized or dextrinized, said matrix material comprising at least one member selected from the group consisting of durum wheat,

semolina, vital wheat gluten, soy protein, hydrocolloids, casein, and gelatin, and at least one plasticizer comprising water,

wherein said encapsulant comprises at least one pharmaceutical component, neutraceutical component, nutritional component, fragrance component, or biologically active component,

wherein the encapsulant and plasticized matrix material form an at least substantially homogeneous mixture,

wherein the amount of said encapsulant is from about 3% by weight to about 50% by weight, based upon the weight of the matrix material, and

wherein the amount of said matrix material is about 40% or more by weight, based upon the weight of the final encapsulated product.

84. An encapsulated product according to claim 83 wherein said matrix material comprises semolina or durum wheat.

85. An encapsulated product according to claim 83 wherein said encapsulant comprises at least one member selected from the group consisting of enzymes and microorganisms.

91. An encapsulated product according to claim 25, comprising about 3% by weight to about 50% by weight of the encapsulant, based upon the weight of the matrix material.

92. An encapsulated product according to claim 25, comprising about 5% by weight to about 20% by weight of the encapsulant, based upon the weight of the matrix material.

93. An encapsulated product according to claim 25, wherein the encapsulant is in liquid form.

95. An encapsulated product according to claim 52, comprising about 3% by weight to about 50% by weight of the encapsulant, based upon the weight of the matrix material.

96. An encapsulated product according to claim 52, comprising about 5% by weight to about 20% by weight of the encapsulant, based upon the weight of the matrix material.

97. An encapsulated product according to claim 83, comprising about 5% by weight to about 20% by weight of the encapsulant, based upon the weight of the matrix material.

101. An encapsulated product according to Claim 25 wherein said plasticized mass comprises from about 60% by weight to about 95% by weight of at least one matrix material.

103. An encapsulated product according to Claim 52 comprising from about 60% by weight to about 95% by weight of the matrix material, based upon the weight of the final encapsulated product.

105. An encapsulated product according to Claim 83 comprising from about 60% by weight to about 95% by weight of the matrix material, based upon the weight of the final encapsulated product.

108. An encapsulated product according to claim 25 wherein said matrix material comprises at least one member selected from the group consisting of durum wheat, semolina, wheat flour, wheat gluten, native or modified starches, soy protein, casein, and gelatin.

109. An encapsulated product according to claim 25 wherein said matrix material comprises at least one member selected from the group consisting of durum wheat, semolina, wheat flour, wheat gluten, native starches and modified starches.

110. An encapsulated product according to claim 27 wherein said matrix material comprises at least one member selected from the group consisting of durum wheat and semolina.

X. EVIDENCE APPENDIX

Webster's New Collegiate Dictionary G& C Merriam Co., Publishers, Springfield, MA page. 223, 1956, was inadvertently omitted as an enclosure to the Amendment After Final Rejection Under 37 CFR 1.116 which was filed on January 21, 2011. but was submitted with a Cover Letter on January 24, 2011. The Webster's definition was apparently considered by the Examiner in the March 1, 2011 Advisory Action. A copy of the Webster's definition is attached:

THIN PAPER

WEBSTER'S NEW COLLEGIATE DICTIONARY

A Merriam-Webster

BASED ON

WEBSTER'S
NEW INTERNATIONAL
DICTIONARY
SECOND EDITION

G. & C. MERRIAM CO., PUBLISHERS
SPRINGFIELD, MASS., U.S.A.

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de·pos'i·to'ry (dē·pŏz'ĭ·tō'rĭ *or, esp. Brit.,* -tẽr·ĭ), *n.; pl.* -RIES (-rĭz).
1. A place where anything is deposited, as for safekeeping or for sale.
2. Depositary (sense 1).
de'pot (dē'pō *or, esp. mil. and Brit.,* dĕp'ō), *n.* [F. *dépôt*, fr. OF.
depost, fr. L. *depositum* a deposit.] **1.** A place of deposit for goods;
a storehouse. **2.** *U.S.* A railroad station. **3.** *Mil.* **a** A storage
point for supplies. **b** A station where recruits are assembled and
trained.
dep'ra·va'tion (dĕp'rȧ·vā'shŭn; dē'prȧ-), *n.* Act of depraving, or state
of being depraved; corruption; depravity.
de·prave' (dē·prāv'), *v. t.* [OF. *depraver* to pervert, fr. L. *depravare*,
depravatum, fr. *de* + *pravus* crooked, perverse, wicked.] **1.** To make
bad; vitiate; corrupt. **2.** *Obs.* To speak ill of; to malign. — **Syn.** See
DEBASE.
de·praved' (-prāvd'), *adj.* Characterized by corruption; esp., per-
verted; evil. — **de·prav'er** (-prāv'ẽr), *n.*
de·prav'i·ty (-prăv'ĭ·tĭ), *n.; pl.* -TIES (-tĭz). **1.** State of being de-
praved; corruption. **2.** A corrupt act or practice.
dep're·cate (dĕp'rē·kāt), *v. t.* [L. *deprecatus*, past part. of *deprecari*
to avert by prayer, deprecate, fr. *de* + *precari* to pray.] **1.** To seek to.
avert, as by prayer. **2.** To express disapproval of. — **dep're·cat'-**
ing·ly (-kāt'ĭng·lĭ), *adv.* — **dep're·ca'tion** (-kā'shŭn), *n.*
dep're·ca'tive (-kā'tĭv), *adj.* Deprecatory. — **dep're·ca'tive·ly**, *adv.*
dep're·ca·to'ry (dĕp'rē·kȧ·tō'rĭ *or, esp. Brit.,* dĕp'rē·kā'tẽr·ĭ), *adj.*
Serving to deprecate; hence, apologetic. — **dep're·ca·to'ri·ly**; *adv.* —
dep're·ca·to'ri·ness, *n.*
de·pre'ci·a·ble (dē·prē'shĭ·ȧ·b'l), *adj.* That can or may be depreciated
in valuation.
de·pre'ci·ate (dē·prē'shĭ·āt; 103), *v. t. & i.* [L. *depretiatus*, past part.
of *depretiare* to depreciate, fr. *de* + *pretiare* to prize, fr. *pretium*
price.] To lessen in price or estimated value; also, to undervalue;
disparage; belittle. — **Syn.** See DECRY. — **Ant.** Appreciate.
de·pre'ci·a'tion (-shĭ·ā'shŭn; -sĭ·ā'shŭn), *n.* A decrease in value;
specif.: **a** Of money, a reduction or loss in exchange value or purchasing
power. **b** A lowering in estimation; disparagement. **c** *Accounting.*
Decline in value of an asset due to such causes as wear or obsolescence.
de·pre'ci·a'tive (dē·prē'shĭ·ā'tĭv; -ȧ·tĭv), *adj.* Depreciatory. — **de-**
pre'ci·a'tive·ly, *adv.*
de·pre'ci·a'tor (-ā'tẽr), *n.* [L.] One who depreciates.
de·pre'ci·a·to'ry (-ȧ·tō'rĭ *or, esp. Brit.,* -ā'tẽr·ĭ, -ȧ·tẽr·ĭ), *adj.* Tending
to depreciate or disparage.
dep're·date (dĕp'rē·dāt), *v. t. & i.* [L. *depraedatus*, past part. of *de-*
praedari, fr. *de* + *praedari* to plunder, fr. *praeda* plunder, prey.] To
plunder; to despoil. — **dep're·da'tor** (-dā'tẽr), *n.* — **dep're·da'to·ry**
(-dā'tō·rĭ; dē·prĕd'ȧ·tō'rĭ *or, esp. Brit.,* -tẽr·ĭ), *adj.*
dep're·da'tion (-dā'shŭn), *n.* Act of despoiling; a ravaging.
de·press' (dē·prĕs'), *v. t.* [OF. *depresser*, fr. L. *depressus*, past part.
of *deprimere*, fr. *de* + *premere* to press.] **1.** *Obs.* To suppress. **2.**
To press down; to let fall; lower. **3.** To lessen the activity, force, etc.,
of; to make dull, as trade. **4.** To lower the pitch of, as the voice.
5. To lessen in value or price; depreciate. **6.** To sadden. — **de-**
press'ing, *adj.* — **de·press'ing·ly**, *adv.*
Syn. **Depress, weigh down** (*or* **weigh on** *or* **upon**), **oppress** mean to load
a person or thing so heavily that he or it sinks under the weight. **De-**
press now chiefly implies a lowering of spirits, of activity, or the like,
by mental or physical causes; **weigh down** (*or* **weigh on** *or* **weigh upon**)
stresses the imposition of difficulty or burden on a person or thing;
oppress stresses the burden which is borne and its effect, such as a
harassing or a subjection to misery.
de·pres'sant (dē·prĕs'ănt; -'nt), *adj.* Lowering functional or vital
activity. — *n.* A depressant drug or other agent.
de·pressed' (dē·prĕst'), *adj.* **1.** Pressed down; hence, dejected; dispir-
ited. **2.** Underprivileged. **3.** *Bot.* Vertically flattened; concave on
the upper surface. **4.** *Zool.* Having the vertical diameter, as of the
body, shorter than the horizontal.
depressed classes. The lowest Indian caste; the untouchables. *Brit.*
de·pres'sion (dē·prĕsh'ŭn), *n.* **1.** Act of depressing, or state of being
depressed. **2.** A place or part that is depressed; a hollow. **3.** De-
jection, as of mind. **4.** Reduction in amount, quality, or force; as, a
phase of the business cycle marked by industrial and commercial stag-
nation, scarcity of goods and money, low prices, and mass unemploy-
ment. **5.** *Astron.* Angular distance of a celestial object below the
horizon; negative altitude. **6.** *Med.* Lowering of vitality or func-
tional activity. **7.** *Meteorol.* A low. **8.** *Psychopathol.* An abnor-
mal state of inactivity and unpleasant emotion, as in manic-depressive
insanity. **9.** *Surv.* The angular distance of an object beneath the hori-
zontal plane that passes through the observer. — **Syn.** See SADNESS.
de·pres'sive (-prĕs'ĭv), *adj.* Tending to depress; characterized by de-
pression. — **de·pres'sive·ly**, *adv.*
de·pres'so·mo'tor (dē·prĕs'ō·mō'tẽr; 2), *adj.* *Physiol.* Inhibiting
movement, or motor response. — *n.* Any depressomotor agent, as
bromides, etc.
de·pres'sor (dē·prĕs'ẽr), *n.* [NL.] **1.** One that depresses. **2.** *Anat.*
A muscle that depresses or draws down a part. **3.** *Physiol.* A nerve
(**depressor nerve**) that decreases the activity or tone of an organ. Cf.
PRESSOR. **4.** *Surg.* An appliance for keeping a part, as the tongue,
out of the way during an operation.
de·priv'al (dē·prīv'ăl), *n.* Act of depriving; deprivation.
dep'ri·va'tion (dĕp'rĭ·vā'shŭn), *n.* Act of depriving, dispossessing, or
bereaving; specif., act of deposing; also, privation; loss.
de·prive' (dē·prīv'), *v. t.* [OF. *depriver*, fr. L. *de* + *privare* to be-
reave, deprive.] **1.** To dispossess; bereave; to hinder from possessing;
debar. **2.** *Obs.* To put an end to; destroy. — **de·priv'a·ble** (-prīv'ȧ-
b'l), *adj.*
‖**de pro·fun'dis** (dē prō·fŭn'dĭs). [L.] Out of the depths; — used of
a cry from the depths of misery.
‖**de pro'pri·o mo'tu** (prō'prĭ·ō mō'tū). [L.] Of one's, or its, own
motion; spontaneously.
dep'side (dĕp'sīd; -sĭd), *n.* Also **dep'sid.** [Gr. *depsein* to tan +
-ide.] *Chem.* Any of a class of tanninlike condensation products of
aromatic hydroxy acids.
depth (dĕpth), *n.* [From DEEP.] **1.** That which is deep; specif., the
watery deep. **2.** An abyss. **3.** **a** Perpendicular measurement down-
ward from the surface; as, the *depth* of a river. **b** Direct linear meas-
urement from the point of view, as backward from the front. **4.** The
midmost part, esp. of something that must be penetrated; also, the
mid-time of a dark or cold season; as, the *depth* of night. **5.** Quality
of being deep; deepness; hence, profoundness. **6.** **a** Lowness of pitch;
as, *depth* of sound. **b** Degree of saturation and brilliance; — said of
colors.
depth charge. An explosive projectile to be used against targets under
water, especially submarines; — called also, erroneously, **depth bomb.**
dep'u·rate (dĕp'ū·rāt; dē·pū'-), *v. t. & i.* [ML. *depuratus*, past part.
of *depurare* to purify, fr. L. *de* + *purare* to purify, fr. *purus* clean,
pure.] To free or become free from impurities. — **dep'u·ra'tion**
(dĕp'ū·rā'shŭn), *n.* — **dep'u·ra'tive** (dĕp'ū·rā'tĭv; dē·pū'rȧ·tĭv), *adj.*
& n. — **dep'u·ra'tor** (-rā'tẽr), *n.*
dep'u·ta'tion (dĕp'ū·tā'shŭn), *n.* **1.** Appointment, as of a deputy;
delegation. **2.** A person or persons deputed to act in one's behalf; a
delegation. **3.** *Obs.* An appointment as gamekeeper, — often used
as a way of giving hunting privileges.
de·pute' (dē·pūt'), *v. t.* [F. *députer*, fr. L. *deputare* to esteem, con-
sider, in LL., to allot, fr. *de* + *putare* to reckon, think.] **1.** To ap-
point as deputy or agent; to delegate. **2.** To assign as to a deputy.
dep'u·tize (dĕp'ū·tīz), *v. t. & i.* To appoint, or to act, as deputy.
dep'u·ty (-tĭ), *n.; pl.* -TIES (-tĭz). [F. *député*, prop. past part.] **1.**
One appointed to act for another; a substitute. **2.** A member of a leg-
islative chamber known as the Chamber of Deputies. — **Syn.** See
AGENT.
de·rac'i·nate (dē·răs'ĭ·nāt), *v. t.* [F. *déraciner*, fr. *dé-* (fr. L. *dis-*) +
racine root, fr. L. *radix*, *radicis*, root.] To pluck up by the roots;
extirpate. — **de·rac'i·na'tion** (-nā'shŭn), *n.*
de·raign' (dē·rān'), *v. t.* [OF. *deraisnier* to allege, plead, fr. *de-* (fr.
L. *de*) + *raisnier* to speak, reason, deriv. of L. *ratio* reason.] *Now*
Rare. Law. To prove or vindicate, esp. by wager of battle. — ***de-***
raign battle, combat, etc. To battle; to array for battle.
de·rail' (dē·rāl'), *v. t.* [F. *dérailler*, fr. *dé-* (see DE-, 4) + *rail* rail, fr.
E.] To cause to run off the rails. — **de·rail'ment**, *n.*
de·range' (dē·rānj'), *v. t.*; see RANGE. [F. *déranger*, fr. *dé-* (fr. L.
dis-) + *ranger* to range.] **1.** To disorder; disarrange. **2.** To disturb
in action or function, as a part or organ, or the whole of a machine or
organism. **3.** To render insane.
de·ranged' (dē·rānjd'), *adj.* Disordered; insane.
de·range'ment (-rānj'mĕnt), *n.* Disarrangement; confusion; esp.,
mental disorder; insanity.
de·ray' (dē·rā'), *n.* [OF. *desrei*, fr. *des-* (fr. L. *dis-*) + *rei* order.]
Archaic. Disorder; esp., disorderly merriment.
Der'by (dûr'bĭ *or, esp. for sense* 1, där'bĭ; *in England usually* där'-
bĭ), *n.* **1.** (*pron.* där'bĭ) A race for three-year-old horses, instituted
in 1780 by the earl of Derby, and run annually at Epsom (near Lon-
don) over a course 1½ miles and 29 yards long. **2.** (*pron.* dûr'bĭ *or*
där'bĭ) A race or contest of similar prominence of its kind; as, the Ken-
tucky *Derby*. **3.** [*not cap.*] A race or contest open to all comers; as, a
trout *derby*; bicycle *derby*. **4.** (*pron.* dûr'bĭ; *Brit.* där'bĭ) [*not cap.*]
A stiff felt hat with a dome-shaped crown; a bowler. **5.** [*not cap.*] *pl.*
Handcuffs; darbies.
dere (dēr). Var. of NEAR, hard.
‖**de rè'gle** (dĕ râ'gl'). [F.] According to proper form.
der'e·lict (dĕr'ē·lĭkt), *adj.* [L. *derelictus*, past part. of *derelinquere*
to abandon, fr. *de* + *relinquere* to leave.] **1.** Given up by the owner;
abandoned. **2.** *Chiefly U.S.* Unfaithful; neglectful. — *n.* **1.** A
vessel abandoned on the high seas and constituting a menace to navi-
gation. **2.** *Law.* **a** A thing voluntarily abandoned. **b** A tract of land
left dry by water receding from its former bed. **3.** A person aban-
doned, or outside the pale of respectable society; a "human wreck."
4. *U.S.* One guilty of neglect of duty.
der'e·lic'tion (-lĭk'shŭn), *n.* **1.** Abandonment; an utter forsaking.
2. State of being abandoned. **3.** A failure in duty; shortcoming. **4.**
Law. A retiring of a body of water, so that land above high-water mark
is gained.
de·ride' (dē·rīd'), *v. t.* [L. *deridere*, *derisum*, fr. *de* + *ridere* to
laugh.] To laugh at with contempt; to mock. — **Syn.** See RIDICULE.
— **de·rid'er** (-rīd'ẽr), *n.* — **de·rid'ing·ly**, *adv.*
‖**de ri·gueur'** (dĕ rē'gûr'). [F.] According to strict etiquette; obliga-
tory for good form.
de·ris'i·ble (dē·rĭz'ĭ·b'l), *adj.* Worthy of derision or scorn.
de·ri'sion (dē·rĭzh'ŭn), *n.* **1.** Act of deriding, or state of being derided.
2. An object of derision or scorn.
de·ri'sive (dē·rī'sĭv), *adj.* Expressing, serving for, or characterized by
derision. — **de·ri'sive·ly**, *adv.* — **de·ri'sive·ness**, *n.*
de·ri'so·ry (dē·rī'sō·rĭ), *adj.* Derisive.
de·riv'a·ble (dē·rīv'ȧ·b'l), *adj.* That can be derived.
der'i·va'tion (dĕr'ĭ·vā'shŭn), *n.* **1.** Act or process of deriving or draw-
ing from a source; transmission. **2.** That from which a thing is de-
rived; origin. **3.** *Math.* The operation of deducing one function from
another according to some fixed law. **4.** *Philol.* The development of
a word from its more original or radical elements; also, the tracing or a
statement of this process. — **der'i·va'tion·al**, *adj.*
de·riv'a·tive (dē·rĭv'ȧ·tĭv), *adj.* Derived, transmitted, or educed;
hence, not radical, original, or fundamental. — *n.* **1.** Anything ob-
tained or deduced from another. **2.** *Chem.* A substance so related to
another substance by modification or partial substitution as to be re-
garded as derived from it, even when not obtainable from it in prac-
tice; thus, the amino compounds are *derivatives* of ammonia. **3.**
Gram. **a** A word derived from another by any process of word develop-
ment, as by adding a prefix or suffix. **b** = COMPOUND, *n.*, 3 c. — **de-**
riv'a·tive·ly, *adv.*
de·rive' (dē·rīv'), *v. t.* [OF. *deriver*, fr. L. *derivare*, fr. *de* + *rivus*
stream, brook.] **1.** To gather by inference; deduce. **2.** *Obs.* To
cause to come; bring down (*upon*). **3.** To receive, as from a source or
origin; — followed by *from*; as, a custom *derived* from paganism. **4.**
To trace the origin, descent, or derivation of. **5.** *Chem.* To obtain by
actual or theoretical substitution from another substance. — *v. i.* To
take origin; to proceed; to be deduced. — **Syn.** See SPRING. — **de-**
riv'er (-rīv'ẽr), *n.*
-derm (-dûrm). [Gr. *derma*, *-atos*, skin, fr. *derein* to flay.] A suffix
signifying *skin*, *integument*, *covering*, as in blasto*derm*, ecto*derm*.
der'ma (dûr'mȧ), *n.* [NL. See -DERM.] *Anat. & Zool.* The sensi-
tive layer of the skin beneath the epidermis. — **der'mal** (-măl), *adj.*
der'ma·to- (dûr'mȧ·tō-), **dermat-**. [See -DERM.] A combining form
meaning *skin*, *hide*, as in **der'ma·ti'tis** (see -ITIS).
der·mat'o·gen (dẽr·măt'ō·jĕn; dûr'mȧ·tō·jĕn), *n.* [*dermato-* + *-gen.*]
Bot. The thin external layer of primary meristem covering the growing
points, esp. of roots, and giving rise to the epidermis.
der'ma·tol'o·gy (dûr'mȧ·tŏl'ō·jĭ), *n.* [*dermato-* + *-logy.*] The sci-
ence which treats of the skin, its structure, functions, and diseases.

XI. RELATED PROCEEDING APPENDIX

None.